PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

LOTRONEX
(alosetron)

Status: CVS Caremark Criteria ***Ref# 129-A***
Type: Initial Prior Authorization ***Ref# 690-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Lotronex is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:

- chronic IBS symptoms (generally lasting six months or longer),
- had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
- not responded adequately to conventional therapy.

Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following:

- frequent and severe abdominal pain/discomfort,
- frequent bowel urgency or fecal incontinence,
- disability or restriction of daily activities due to IBS.

Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable.

Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for a biological female or a person that self-identifies as a female with a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)

AND

- The patient has experienced chronic irritable bowel syndrome (IBS) symptoms lasting at least 6 months

AND

- Gastrointestinal tract abnormalities have been ruled out

AND

- The patient has had an inadequate response to conventional therapy

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Lotronex is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have: chronic IBS symptoms (generally lasting six months or longer), had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and not responded adequately to conventional therapy.

Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.

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REFERENCES

1. Lotronex [package insert]. Roswell, GA: Sebela Pharmaceuticals Inc.; April 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed August 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed August 2020.

Written by:	UM Development (LS)
Date Written:	09/2003
Revised:	(JG) 11/2002; (MG) 08/2003; (CM) 09/2004; (JG) 10/2005; (CT) 06/2006, 05/2007, 06/2008, 06/2009, 06/2010, 07/2011, 07/2012; 10/2012 (extended duration), 08/2013; (JH) 08/2014, 08/2015; (KM) 08/2016 (removed safety question, removed female from question 1), 09/2016 (updated wording of criteria for approval to not discriminate for TGC patients); (DS) 08/2017 (no clinical changes); (JG) 09/2018 (no clinical changes); (DS) 09/2019 (no clinical changes; combined criteria; removed MDC); (PM) 08/2020 (no clinical changes)
Reviewed:	Medical Affairs 02/11/2000, 08/2000, 11/2002, 08/2003; (MM) 10/2004, 10/2005, 06/2006; (WF) 05/2007, 06/2008, 06/2009; (KP) 06/2010, 07/2011, (LB) 07/2012; (KP) 08/2013; (KC) 08/2014; (MC) 08/2015: (ME) 08/2016; (CHART) 09/26/2019; (CHART) 09/24/2020 External Review: 02/2003, 10/2003, 11/2004, 12/2006, 12/2007, 12/2008, 12/2009, 02/2011, 02/2012, 04/2013, 12/2013, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 12/2019, 12/2020

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for a biological female or a person that self-identifies as a female with a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)? [If no, then no further questions.]	Yes	No
2	Has the patient experienced chronic irritable bowel syndrome (IBS) symptoms lasting at least 6 months? [If no, then no further questions.]	Yes	No
3	Have gastrointestinal tract abnormalities been ruled out? [If no, then no further questions.]	Yes	No
4	Has the patient had an inadequate response to conventional therapy?	Yes	No

Mapping Instructions (129-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are a biological female or you self-identify as female and you have severe diarrhea-predominant irritable bowel syndrome (IBS). Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had irritable bowel syndrome (IBS) symptoms for at least 6 months. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]

3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had gastrointestinal tract abnormalities ruled out. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
4.	Approve, 36 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when other therapies did not work for you. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]

Mapping Instructions (690-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are a biological female or you self-identify as female and you have severe diarrhea-predominant irritable bowel syndrome (IBS). Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had irritable bowel syndrome (IBS) symptoms for at least 6 months. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had gastrointestinal tract abnormalities ruled out. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
4.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when other therapies did not work for you. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]